Introduced by Senator Ducheny (Coauthors: Senators Bowen, Kuehl, and Soto)

(Coauthor: Assembly Member Laird)

February 21, 2003

An act to amend Sections 1208, 1212, and 1217 1217, 1228, and 1231 of, and to add Sections 1218.1, 1218.2, 1226.1, and 1226.3 to 1226.1, 1226.2, 1226.3, and 1229.1 to, and to add and repeal Section 1218.2 of, the Health and Safety Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

SB 937, as amended, Ducheny. Clinics: licensure and operation.

(1) Under existing law, the State Department of Health Services regulates the licensure and operation of clinics, including community clinics and primary care clinics, as defined. Existing law authorizes the department to provide consulting services upon request to any clinic to assist in the identification and correction of deficiencies.

Existing law requires any person, firm, association, partnership, or corporation desiring a license for a clinic or a special permit for special services to file a verified application with the department containing specified information.

Existing law authorizes the department to issue a license to an applicant only if it meets all requirements for clinic licensure, except that it proposes to operate its clinic out of an existing facility that does not satisfy certain applicable building requirements for the physical plant, provided that (1) the applicant establishes that, where possible and feasible, applicable building requirements have been met, and (2) the applicant submits a specified plan of modernization. Existing law

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authorizes the Director of Health Services to waive building requirements for primary care clinics when certain conditions are satisfied.

This bill would revise provisions relating to the licensure and operation of clinics, including authorizing the department to charge a reasonable fee for the above consulting services, not to exceed \$100 per hour, when the consulting services are provided onsite at the clinic or its administrative offices.

This bill would provide that an application is not required where a primary care clinic adds a service other than a special service, or modifies an existing primary care clinic site, but would require the clinic to notify the department of the changes in service or physical plant.

This bill would require, rather than authorize, the department to issue a license to a primary care clinic that meets specified building requirements. The bill would provide that a clinic's submission of a signed statement from a licensed architect, local building department, or general contractor certifying the clinic's compliance with applicable building standards shall be deemed satisfactory evidence to the department for purposes of licensure under the above circumstances.

This bill would also require, rather than authorize, the director to waive building requirements for primary care clinics when specified conditions are satisfied. The bill would require primary care clinics to conform to minimum construction standards of adequacy and safety for the physical plant, under the exclusive jurisdiction of the local building department.

This bill would authorize a primary care clinic that has held a valid, unrevoked, and unsuspended license for at least 5 years to apply for, and receive, a license to establish an affiliate clinic, without first conducting an initial onsite survey, in accordance with criteria set forth by the bill.

This bill would require the department, *until January 1, 2010*, to issue a single consolidated license to a primary care clinic meeting specified requirements that includes more than one physical plant maintained and operated on separate premises. This bill would require a community *primary care* clinic to comply with specified state requirements for public health protection for clinic personnel and volunteers. The bill would also prohibit the department from requiring a primary care clinic to utilize a registered nurse, absent a determination by the professional director of the clinic that nursing services are required. The bill would also prohibit the department from taking

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specified regulatory, policy, or enforcement actions regarding nurses working in a primary care clinic without the written concurrence of the Board of Registered Nursing.

(2) Existing law requires every clinic to be inspected in accordance with specified criteria. Existing law exempts certain facilities from this inspection requirement.

This bill would add a primary care clinic with specified accreditation to the list of clinics that are exempt from this inspection requirement.

(3) Existing law requires the department to notify a clinic of all deficiencies in its compliance with the provisions relating to clinic licensure and operations.

This bill would prohibit the imposition of a notification of deficiency, fine, sanction, or denial, suspension, or revocation of licensure against a clinic for violation of a regulation, under specified circumstances.

(4) Existing law requires the Office of Statewide Health Planning and Development, in consultation with the Community Clinics Advisory Committee, to prescribe minimum construction standards for adequacy and safety for the physical plant of clinics.

This bill would require the Director of Health Services to appoint a minimum of 15 members to the committee, and would specify requirements for membership and meetings. It would also specify the manner in which a clinic may establish compliance with the specified standards for construction adequacy and safety.

(5) Existing law requires a clinic to comply with licensing requirements, but allows a clinic to deviate from these requirements under certain circumstances, upon written request and substantiating evidence submitted by the clinic, and with the prior written approval of the department.

This bill would state that a primary care clinic is deemed to have submitted substantiating evidence for use of alternatives to personnel requirements if the primary care clinic is in a medically underserved area or a health professional shortage area, or if the clinic serves a medically underserved population.

(6) Under existing law, violation of the provisions relating to clinics is a misdemeanor.

By imposing new requirements on the licensure and operation of clinics, this bill would create new crimes, thereby imposing a state-mandated local program.

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(7) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the 2 following:

- (a) California's primary care clinics are essential partners with the state in providing a health care safety net for underserved, uninsured, and underinsured populations in a cost-effective manner.
- (b) California's primary care clinics generate significant savings to the state and to local communities by providing primary and preventive care that responds to patients' needs before medical problems become serious or life-threatening, and by reducing the reliance of patients, including the uninsured and underinsured, on costly emergency room care, inpatient treatment and specialty care.
- (c) Primary care clinics operate most similarly to private doctors' offices, but are required to comply with complicated, burdensome regulations more suited to hospitals, skilled nursing facilities, and other facilities intended to meet the 24-hour care needs of medically fragile patients.
- (d) The need for primary care clinics is growing dramatically due to the continuing increase of uninsured and underinsured patients in California, an escalating unemployment rate, and a severely depressed economy.
- (e) The current system of licensing primary care clinics is out of step with contemporary health care delivery systems, and results in a significant waste of taxpayer and community resources that could otherwise be devoted to patient care.
- (f) Administrative streamlining of the licensure of new and continuing primary care clinics will result in substantial cost

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savings to the state and improved access to health care for 2 underserved populations.

- SEC. 2. Section 1208 of the Health and Safety Code is amended to read:
- 1208. (a) The department may provide consulting services upon request to any clinic to assist in the identification or correction of deficiencies to ensure that a high quality of care is provided by the clinic.
- (b) The department may charge a reasonable fee for the 10 services described in subdivision (a), not to exceed one hundred dollars (\$100) per hour. This fee may be charged only for consulting services provided onsite at the clinic or its administrative offices. Under no circumstances shall the department require a clinic to use the consulting services authorized by this section.
 - SEC. 3. Section 1212 of the Health and Safety Code is amended to read:
 - 1212. (a) Any person, firm, association, partnership, or corporation desiring a license for a clinic or a special permit for special services under the provisions of this chapter, shall file with the department a verified application on forms prescribed and furnished by the department, containing the following:

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(1) Evidence satisfactory to the department that the applicant is of reputable and responsible character. If the applicant is a firm, association, partnership, trust, corporation, or other artificial or legal entity, like evidence shall be submitted as to the members, partners, trustees or shareholders, directors, and officers thereof and as to the person who is to be the administrator of, and exercise control, management, and direction of the clinic for which application is made.

(b)

(2) If the applicant is a partnership, the name and principal business address of each partner, and, if any partner is a corporation, the name and principal business address of each officer and director of the corporation and name and business address of each stockholder owning 10 percent or more of the stock thereof.

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(3) If the applicant is a corporation, the name and principal business address of each officer and director of the corporation, and where the applicant is a stock corporation, the name and principal business address of each stockholder holding 10 percent or more of the applicant's stock and, where any stockholder is a corporation, the name and principal business address of each officer and director of the corporate stockholder.

(d)

(4) Evidence satisfactory to the department of the ability of the applicant to comply with the provisions of this chapter and rules and regulations promulgated under this chapter by the department.

(e)

(5) The name and address of the clinic, and if the applicant is a professional corporation, firm, partnership, or other form of organization, evidence that the applicant has complied with the requirements of the Business and Professions Code governing the use of fictitious names by practitioners of the healing arts.

(f)

(6) The name and address of the professional licentiate responsible for the professional activities of the clinic and the licentiate's license number and professional experience.

(g)

(7) The class of clinic to be operated, the character and scope of advice and treatment to be provided, and a complete description of the building, its location, facilities, equipment, apparatus, and appliances to be furnished and used in the operation of the clinic.

(h)

(8) Sufficient operational data to allow the department to determine the class of clinic that the applicant proposes to operate and the initial license fee to be charged.

(i)

(9) Any other information as may be required by the department for the proper administration and enforcement of this chapter, including, but not limited to, evidence that the clinic has a written policy relating to the dissemination of the following information to patients:

(1)

(A) A summary of current state laws requiring child passenger restraint systems to be used when transporting children in motor vehicles.

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(*B*) A listing of child passenger restraint system programs located within the county, as required by Section 27360 or 27362 of the Vehicle Code.

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(C) Information describing the risks of death or serious injury associated with the failure to utilize a child passenger restraint system.

(i)

(10) Applicants for a license or special permit covering a project within the meaning of Section 127170 shall submit a copy of a certificate of need as required by the department.

(k)

- (b) (1) No application is required where a licensed primary care clinic adds a service that is not a special service, as defined in Section 1203, or any regulation adopted thereunder, or remodels or modifies an existing primary care clinic site. However, the clinic shall notify the department, in writing, of the change in service or physical plant.
- (2) Where the *primary care* clinic remodels or modifies its existing physical plant, the notification to the department shall include a signed statement from a licensed architect, *or* a local building department, or a general contractor that certifies that any physical alterations are in compliance with the minimum standards of adequacy, safety, and sanitation of the physical plant, pursuant to subdivision (b) of Section 1217 construction standards of adequacy and safety for the physical plant, pursuant to subdivision (b) of Section 1226 and that the individual signing the statement is competent to determine that compliance.
- (c) In the course of fulfilling its obligations under Section 1221.09, the department shall ensure that any primary care clinic application form requiring information of the type specified in subdivisions (a), (d), (h), or (i), is consistent with the requirements of Section 1225, including the requirement that rules and regulations for primary care clinics be separate and distinct from the rules and regulations for specialty clinics.
- (d) The department shall ensure that any information required for submission to the department pursuant to this chapter is specifically required by state or federal statute or regulation.

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 SEC. 4. Section 1217 of the Health and Safety Code is amended to read:

- 1217. (a) An applicant for a license to operate a primary care clinic, as specified in subdivision (a) of Section 1204 that meets all requirements for licensure under this chapter, except that it proposes to operate its clinic out of an existing facility that does not satisfy all of the applicable building requirements for the physical plant, other than fire and life safety requirements, shall be issued a license by the state department if both of the following requirements are met:
- (1) The applicant establishes, by evidence satisfactory to the state department, that, where possible and feasible, the applicable building requirements have been met.
- (2) The applicant submits a plan of modernization acceptable to the state department that sets forth the proposed changes to be made, during a period not to exceed three years from the date of initial licensure, to bring the applicant's facility into substantial conformance with applicable building requirements.
- (b) Evidence that shall automatically be deemed to be satisfactory to the department for purposes of subdivision (a), or for purposes of establishing substantial compliance with the minimum standards of adequacy, safety, and sanitation of the physical plant under this chapter, including Section 1226, and Section 1765.140, shall include the primary care clinic's submission of a statement from a licensed architect, a local building department, or a general contractor indicating compliance with the minimum construction standards described in subdivision (b) of Section 1226, and certifying that the individual signing the letter is competent to determine that compliance.

(c)

- (b) Failure to complete the plan of modernization as approved and within the time allowed shall constitute a basis for revocation or nonrenewal of the applicant's license unless the applicant earlier applies for and obtains a waiver from the department. The director shall waive building requirements for primary care clinics where he or she determines all of the following conditions are met:
- (1) That the requirements cannot be met by an applicant, or that they can be met only at an unreasonable and prohibitive cost.
- (2) That the requirements are not essential to protect the health and safety of the clinic staff or the public it serves.

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(3) That the granting of the waiver applied for is in the public interest.

- (d) A primary care clinic shall conform to the minimum construction standards of adequacy and safety for the physical plant of clinics, as determined under subdivision (b) of Section 1226. Compliance with those requirements is within the exclusive jurisdiction of the local building department.
- SEC. 5. Section 1218.1 is added to the Health and Safety Code, to read:
- 1218.1. A primary care clinic that has held a valid, unrevoked, and unsuspended license for at least the immediately preceding five years, and that has no pending action to suspend or revoke its license, may file an application under this section to establish an affiliated a primary care clinic at an additional site, which shall hereafter be referred to as the affiliate clinic. The department, upon receipt of the completed application, shall issue a license to the affiliated affiliate clinic, without first conducting an initial onsite survey, under the following conditions:
- (a) The existing primary care clinic, which shall *hereafter* be referred to in this section as the parent clinic, has submitted an *a completed* application for licensure *for the affiliate clinic* and the associated application fee which shall be referred to in this section as the affiliate clinic.
- (b) The parent and affiliate clinics' corporate officers are the same, with the exception of any site providing only dental or podiatric services and which are permitted to have a dentist or podiatrist as its professional director., as specified in Section 5213 of the Corporations Code, are the same.
- (c) The parent and affiliate elinic clinics are both owned and operated by the same nonprofit organization with the same board of directors.
- (d) The parent and affiliate clinics' operational policies and procedures are substantially identical the same.
- (e) The parent and affiliate elinic clinics both follow substantially the same training, competency testing, and quality assurance standards for health care staff performing the same or similar functions. If an affiliate clinic will be providing primary care services different from the parent clinic, the professional director shall develop training, competency testing, and quality assurance standards in conjunction with the appropriate

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personnel at the affiliate clinic. It shall not be necessary for the professional director to be the same for all sites.

- (f) The parent clinic has submitted evidence to the department establishing compliance with the minimum standards of adequacy, safety, and sanitation of the satellite's physical plant as provided under subdivision (b) of Section 1217. establishing compliance with the minimum construction standards of adequacy and safety of the affiliate clinic's physical plant pursuant to subdivision (b) of Section 1226.
- (g) Nothing in this section shall prohibit the department from conducting a licensing inspection at any time after receipt of the completed application.
- SEC. 6. Section 1218.2 is added to the Health and Safety Code, to read:
- 1218.2. (a) Notwithstanding any other provision of law, the department, upon application of a primary care clinic that meets all the criteria of subdivision (b); and other applicable requirements of licensure, shall issue a single consolidated license to a primary care clinic that includes more than one physical plant maintained and operated on separate premises.
- (b) The issuance of a single consolidated license shall be based on all of the following criteria:
- (1) There is a single governing body for all of the clinic sites maintained and operated by the licensee.
- (2) There is a single administration for all of the clinic sites maintained and operated by the licensee.
- (3) All policies and procedures for clinic employees apply to all clinic sites. However, it shall not be required for any staff member clinic sites. However, no staff member shall be required to perform services at more than one facility.
- (4) All training, competency testing, and quality assurance standards are *substantially* identical for all of the clinic sites.
- (c) In issuing the single consolidated license, the department shall specify the location of each facility, as designated by the applicant. The single consolidated license shall be renewed annually. The initial fee and each annual fee shall be thirty dollars (\$30) per clinic site.
- (d) A primary care clinic that is issued a single consolidated license pursuant to this section, at its option, may receive from the department a single Medi-Cal program provider number or

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separate Medi-Cal program provider numbers for one or more of the facilities subject to the single consolidated license. Irrespective of whether the primary care clinic is issued one or more Medi-Cal provider numbers, a rural health clinic or federally qualified health center may file separate cost reports for each facility with the approval of the department, if being reimbursed on a reasonable cost basis.

- (e) For purposes of preparing the Annual Utilization Report of Primary Care Clinics, the department and the Office of Statewide Health Planning and Development may require reporting of service utilization data separately by each facility of a primary care clinic issued a single consolidated license pursuant to this section.
- (f) If an individual clinic site fails to comply with the licensing requirements, is issued a an identification of deficiencies under Section 1229, or fails to comply with any rule or regulation promulgated by the department, the lack of compliance shall affect only the individual site, and shall not affect the other sites listed on the consolidated license. only the license of the individual site, and shall not affect any other compliant sites listed on the consolidated license.
- (g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date. The repeal of this section shall in no way affect the continued validity of licenses issued prior to the repeal.
- SEC. 7. Section 1226.1 is added to the Health and Safety Code, to read:
- 1226.1. A community primary care clinic shall comply with department requirements regarding annual health examinations, vaccination, or other public health protections for clinic personnel and volunteers, which shall be no more burdensome stringent than requirements applied to acute care hospitals health facilities licensed under Chapter 2 (commencing with Section 1250).
- SEC. 8. Section 1226.3 is added to the Health and Safety Code, to read:
- 1226.3. (a) The department may not require a primary care elinic to utilize a registered nurse unless nursing services are required, as determined in the sole discretion of the professional director of the clinic.

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(b) No regulation, advisory, policy, or enforcement effort of the department regarding the scope of practice or appropriate assignment of registered nurses, nurse practitioners, certified nurse midwives, nurse anesthetist, or other advanced practice nurses by a primary care clinic shall be implemented without the written concurrence of the Board of Registered Nursing.

SEC. 9.

- SEC. 8. Section 1226.2 is added to the Health and Safety Code, to read:
- 1226.2. The director shall appoint a minimum of 15 members to the Community Clinics Advisory Committee provided for in subdivision (b) of Section 1226. This committee shall meet on an ad hoc basis and shall be composed of individuals who are employed or under contract to provide services to a community clinic on a full-time basis, as well as representatives of at least three nonprofit associations that represent 50 or more community clinic sites each.
- SEC. 9. Section 1226.3 is added to the Health and Safety Code, to read:
- 1226.3. A primary care clinic may establish compliance with the minimum construction standards of adequacy and safety for the physical plant described in subdivision (b) of Section 1226 by submitting a written statement from a licensed architect or a local building department certifying that the applicable construction, remodeling, alteration, or other applicable modification of the physical plant is in compliance with these standards, and that the individual signing the statement is competent to determine that compliance. Enforcement of compliance with applicable provisions of the building code, pursuant to subdivision (b) of Section 1226, shall be within the exclusive jurisdiction of the local building department.
- SEC. 10. Section 1228 of the Health and Safety Code is amended to read:
- 1228. Every (a) Except as provided in subdivision (c), every clinic for which a license or special permit has been issued, except a rural health clinic, ambulatory surgical center, end-stage renal disease facility, and comprehensive outpatient rehabilitation facility that is certified to participate either in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, or the medicaid program under Title

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1 XIX (42 U.S.C. Sec. 1396 et seq.) of the federal Social Security
2 Act, or both, shall be periodically inspected. The frequency of
3 inspections shall depend upon the type and complexity of the
4 clinic, or special service to be inspected. Inspections shall be
5 conducted no less often than once every two years and as often as
6 necessary to insure ensure the quality of care being provided.
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- (b) (1) During inspections, representatives of the state department shall offer such any advice and assistance to the clinic as they deem appropriate. The state department may contract with local health departments for the assumption of any of the state department's responsibilities under this chapter. In exercising the this authority so delegated, the local health department shall conform to the requirements to this chapter and to the rules, regulations, and standards of the state department. The state
- (2) The department shall reimburse local health departments for services performed pursuant to this section, and such these payments shall not exceed actual cost. Reports of each inspection shall be prepared by the representative conducting it upon forms prepared and furnished by the department and filed with the state department.
 - (c) This section shall not apply to any of the following:
 - (1) A rural health clinic.

- (2) A primary care clinic accredited by either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAAHC).
 - (3) An ambulatory surgical center
 - (4) An end-stage renal disease facility.
- (5) A comprehensive outpatient rehabilitation facility that is certified to participate either in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, or the medicaid program under Title XIX (42 U.S.C. Sec. 1396 et seq.) of the federal Social Security Act, or both.
- 35 SEC. 11. Section 1229.1 is added to the Health and Safety 36 Code, to read:
 - 1229.1. No notification of deficiency, civil or criminal penalty, fine, sanction, or denial, suspension, or revocation of licensure, may be imposed against a primary care clinic, or any person acting on behalf of the clinic, for a violation of a regulation,

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as defined in Section 11342.600 of the Government Code, if any of the following circumstances exists:

- (a) The regulation was not adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.
- (b) The regulation failed to give the primary care clinic, including any person acting on their behalf, fair warning of the conduct that the regulation prohibited or required.
- (c) The primary care clinic or person acted in reasonable 10 reliance upon written representations about what the regulation prohibits or requires that were issued by the department, including a delegate of the department under Section 1228, with actual or apparent authority to interpret, administer, or enforce the regulations.
- SEC. 12. Section 1231 of the Health and Safety Code is 16 amended to read:
- 1231. (a) All clinics shall maintain compliance with the 18 licensing requirements. Such These requirements shall not, however, prohibit the use of alternate concepts, methods, procedures. techniques, space, equipment, qualifications, or the conducting of pilot projects, provided such these exceptions are carried out with provision for safe and adequate patient care and with prior written approval of the state department. A written request and substantiating evidence supporting the request shall be submitted by the applicant or licensee to the state department. The state department shall approve or deny such any request within 60 days of submission. Such This approval shall be in writing and shall provide for the terms and conditions under which the exception is granted. A denial shall be in writing and shall specify the basis therefor.

(b) A primary care clinic shall be deemed to have submitted sufficient substantiating evidence supporting a request for utilization of alternatives to personnel requirements contained in regulations adopted under this chapter if the clinic is in a geographic area that is either deemed under federal law, or designated by the Office of Statewide Health Planning and Development, as a medically underserved area, a health professional shortage area, or as serving, in whole or in part, a medically underserved population.

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(c) If after investigation the state department determines that a clinic granted a waiver pursuant to this section is operating in a manner contrary to the terms or conditions of the waiver, the director shall immediately revoke the waiver.

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SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.